

The cost of a deep cut

European countries have been struggling with increasing pharmaceutical expenditure. Cost-containment is a major thrust area for policy reforms of pharmaceutical pricing and reimbursement in Europe, writes **Ranjith Gopinathan** of Frost & Sullivan.

In 2010, a substantial drug price cut was made across Europe, a significant concern considering that Europe is the world's second-largest pharma market, only slightly smaller than the US. In Germany, the rebate that drug firms must pay insurers for drugs outside the country's reference-price system was hiked by 10%.

Governments of various European countries have implemented several supply-side and demand-side measures to control rising healthcare costs. A range of policies exists, including generic substitution, patient co-payments, physician drug budgets and price controls. Such mechanisms influence the price setting of manufacturers indirectly.

There are multiple frameworks for the regulation of prices and distribution margins in Europe. Most European countries have price regulations for reimbursable medicines and pharmacy margins. Cost effectiveness, relative effectiveness and unmet medical needs are some of the key criteria for drug reimbursement decisions. Moreover, health technology assessment (HTA) is increasingly important as a criterion for decision-making.

Ensuring sustainable financing of health systems is critical for governments, because healthcare expenditure as a share of GDP is projected to rise further due to expensive new medical technologies and the growth in ageing populations. European governments are under immense pressure to cut pharmaceutical expenditure. As a result, they have even resorted to adopting various direct and indirect price control mechanisms.

Generics' critical role

Generics are widely regarded as the best route to allow access to safe, effective and high-quality drugs at affordable prices for the majority of patients. In addition, generics play a vital role in the development of sustainable healthcare models in European countries as they have a direct influence on pharmaceutical spending.

The generics industry throughout most of Europe is highly competitive and this works as an indirect factor by adding to the pressure on the pharmaceutical industry to develop newer, more innovative drugs. With factors such as ageing populations and



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expensive drugs driving healthcare costs upwards, generic medicines have a critical role to play in the European pharmaceuticals market.

Individual countries in Europe have separate national legislation to govern the use of generic drugs. This reflects the underlying attitude towards the provision and financing of healthcare. In addition, government regulations determine the environment in which generic manufacturers need to operate and compete with others. Consequently, the cost savings obtained due to use of generics enable governments to reimburse these innovative drugs.

Reference pricing

Reference pricing is a price control mechanism commonly used across Europe. It can be defined broadly as the maximum reimbursement price arrived at by national health authorities based on comparing drugs from a chemical, pharmacological or therapeutic equivalence perspective.

The main advantage of reference pricing is that it is relatively easy to implement and covers all new and existing drugs. The reference price may aid the generic markets if branded drugs are priced above this level; however, if branded companies reduce their prices below that of the reference price, then the generic manufacturers will suffer due to low profit margins.

Patient co-payment

One of the key aspects of healthcare systems in Europe is patient co-payment. Most European governments reimburse a fixed amount based on either a per prescription model or, depending on the nature of drugs, the economic status of patients; however, there

Table 1. Demand in emerging markets by CROs and CMOs (%), 2011.

European Country	External price reference	All drugs	Reimbursable drugs only	Prescription-only drugs	Statutory pricing	Price negotiations	Other/mix of policies
Austria	X		X		X		
Denmark			X				X
Finland	X		X		X		
France	X		X			X	
Germany			X				X
Greece	X	X			X		
Hungary	X		X				X
Ireland	X		X				X
Italy	X		X			X	
Netherlands	X			X	X		
Poland	X		X				X
Portugal	X			X	X		
Spain	X		X		X		
Sweden			X		X		
UK			X				X

is a significant variation in the way reimbursement is carried out in different countries. This factor is largely influential in helping the patient decide which drug to choose.

Although patient contribution to overall medicine costs is limited in most markets, the respective governments are aiming to involve patients further in terms of their contribution. Patient co-payments in Europe are dependent on the reimbursement structure of individual countries and their payment is usually based on the following mechanisms:

- a fixed amount per prescription
- a percentage cost of the drug prescribed wherein the government reimburses the rest
- the difference in cost of the drug of their choice, in case of expensive innovator medicines for certain diseases
- a mix of all the factors above.

Patient co-payment is commonly practiced in most European countries and it strongly influences the patient's choice of drug. Moreover, cost-containment is also an issue for high-income countries such as Germany and the UK.

Pricing and reimbursement

Reference price systems (for limiting the reimbursement amount) and external price referencing (international price comparisons) are being used more and more in several European countries; however, each country has its own pharmaceutical pricing and reimbursement system. For example, Denmark and Germany have a considerable free-pricing system, but this scenario could change with the implementation of healthcare reforms in 2011. In most European countries there is price control for generic drugs and free pricing for innovator drugs for reimbursement.

A statutory pricing is arrived at between the public payer and the pharmaceutical company for the reimbursement of drugs. In addition, in EU countries such as Cyprus and Ireland, the

reimbursement eligibility depends on the disease indication or the patient population. Denmark and Sweden have a consumption-based reimbursement eligibility, wherein the reimbursement coverage is proportional to the use of the drug.

In most EU countries, the reimbursement lists include drugs that are prescribed at the expense of a third-party payer; however, countries such as Germany, Hungary, Spain and the UK have negative lists that exclude certain drugs from reimbursement. Nonetheless, being included in the reimbursement list does not guarantee 100% reimbursement. In most EU countries, the essential and life-saving drugs receive 100% reimbursement.

Health economics

Health-economic criteria play a significant role in determining the reimbursement policy. Most European countries provide lower reimbursement rates or exemptions from co-payments for low income groups or people with chronic diseases; for example, France and the Netherlands have specific hospital budgets for orphan drugs and high-cost drugs.

Reference pricing alone is not a viable policy for lowering drug cost. Health technology assessment should also be incorporated to assess the value for money of new drugs in various indications and patient subgroups. For example, in the Netherlands, innovative drugs are subjected to health technology assessment in order to assess whether they should be placed in a new cluster and to establish the reference price for that cluster. Some countries like Germany have also introduced maximum reimbursement prices for drugs that are not subject to reference pricing based on HTA.

To successfully contain public pharmaceutical expenditure in the long run, countries should adapt their reimbursement and pricing policies continuously. ■